MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
RADIATION SAFETY SECTION
IONIZING RADIATION RULES

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PART 6. GENERAL REQUIREMENTS FOR THE USE OF DIAGNOSTIC X-RAYS IN THE HEALING ARTS.

This is a new part. The requirements in this part are taken from the SSRCR sections F.3 and F.4 except as otherwise noted. It is created as a separate part in order to simplify the other healing arts parts. This is done by combining common rules for all diagnostic radiation machines into this part rather than repeating them in each of the following parts(7-14).

R325.XXX1. Purpose and scope.

Rule XXX1. This part establishes requirements, for which a registrant is responsible, for use of diagnostic x-ray equipment by, or under the supervision of, an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine. The provisions of this part are in addition to, and not in substitution for, other applicable provisions of these regulations.

R325.XXX2. Definitions A to B.

Rule XXX2. (1) As used in this part:

(a) "Accessible surface" means the external surface of the enclosure or housing of the radiation producing machine as provided by the manufacturer.

(b) "Added filtration" means any filtration which is in addition to the inherent filtration.

(c) "Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.

(d) "Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

(e) "Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.

(f) "Automatic exposure control (AEC)" means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (Includes devices such as phototimers and ion chambers).

(g) "Barrier" (See "protective barrier").

(h) "Beam axis" means a line from the source through the centers of the x-ray fields.

(i) "Beam-limiting device" means a device which provides a means to restrict the dimensions of the x- ray field.

R325.XXX3. Definitions C to D.

Rule XXX3. (1) As used in this part:

(a) "C-arm x-ray system" means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

(b) "Certified components" means components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968, the Food and Drug Administration.

(c) "Certified system" means any x-ray system which has one or more certified component(s).

(d) "Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

(e) "Coefficient of variation (C)" means the ratio of the standard deviation to the mean value of a set of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}} \left[\frac{\sum_{i=1}^{n} (x_i - \bar{x})^2}{n-1} \right]^{1/2}$$

WHERE:

s =Standard deviation of the observed values;

$\bar{x}$ =Mean value of observations in sample;

x_i =I th observation in sample;

n =Number of observations in sample.

(f) "Computed tomography" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

(g) "Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

(h) "Cooling curve" means the graphical relationship between heat units stored and cooling time.

(i) "CT" (See "computed tomography").

(j) "Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

(k) "Detector" (See "radiation detector").

(l) "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

(m)"Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.

(n) "Diagnostic x-ray imaging system" means an assemblage of components for the generation, emission and reception of x-rays and the transformation, storage and visual display of the resultant x-ray image.

(o) "Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See "scattered radiation").

R325.XXX4. Definitions E to H.

Rule XXX4. (1) As used in this part:

(a) "Entrance exposure rate" means the exposure free in air per unit time at the point where the center of the useful beam enters the patient.

(b) "Equipment" (See "x-ray equipment").

(c) "Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

(d) "Filter" means material placed in the useful beam to preferentially absorb selected radiations.

(e) "Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a visible image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

(f) "Focal spot (actual)" means the area projected on the anode of the x-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

(g) "General purpose radiographic x-ray system" means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

(h) "Gonad shield" means a protective barrier for the testes or ovaries.

(i) "Half-value layer" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced by one-half. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

(j) "Healing arts screening" means the testing of human beings using an x-ray machine for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

(k) "Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x second.

(l) "HVL" (See "half-value layer").

R325.XXX5. Definitions I to L.

Rule XXX5. (1) As used in this part:

(a) "Image intensifier" means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher intensity.

(b) "Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

(c) "Image receptor support" means, for mammographic systems, that part of the system designed to support the image receptor during mammography.

(d) "Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

(e) "Irradiation" means the exposure of matter to ionizing radiation.

(f) "Kilovolts peak" (See "Peak tube potential").

(g) "kV" means kilovolts.

(h) "kVp" (see "peak tube potential").

(i) "kWs" means kilowatt second.

(j) "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

(k) "Leakage radiation" means radiation emanating from the diagnostic source assembly except for:

(i) The useful beam; and

(ii) Radiation produced when the exposure switch or timer is not activated.

(l) "Leakage technique factors" means the technique factors associated with the diagnostic source assembly which are used in measuring leakage radiation. They are defined as follows:

(i) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being

10 millicoulombs, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger;

(ii) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential;

(iii) For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

(m) "Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

(n) "Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:

Percent line-voltage regulation = $100\ (V_n - V_l)/V_l$

where: V_n = No-load line potential; and

V_l = Load line potential.

R325.XXX6. Definitions M to P.

Rule XXX6. (1). As used in this part:

(a) "mA" means milliampere.

(b) "mAs" means milliampere second.

(c) "Maximum line current" means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.

(d) "Mobile x-ray equipment" (see "x-ray equipment").

(e) "Patient" means an individual or animal subjected to healing arts examination, diagnosis, or treatment.

(f) "PBL" See "positive beam limitation."

(g) "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

(h) "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

(i) "PID" (See "position indicating device").

(j) "Portable x-ray equipment" (See "x-ray equipment").

(k) "Position indicating device" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

(l) "Positive beam limitation" means the automatic or semi-automatic adjustment of an x-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

(m)"Primary protective barrier" (See "protective barrier").

(n) "Protective apron" means an apron made of radiation absorbing materials used to reduce radiation exposure.

(o) "Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

(i) "Primary protective barrier" means the material, excluding filters, placed in the useful beam;

(ii) "Secondary protective barrier" means the material which attenuates stray radiation.

(p) "Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.

R325.XXX7. Definitions Q to S.

Rule XXX7. (1) As used in this part:

(a) "Qualified expert" means an individual who has demonstrated to the satisfaction of the Agency that such individual possesses the knowledge, training and experience to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs.

(b) "Radiation detector" means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

(c) "Radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

(d) "Radiograph" means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

(e) "Radiographic imaging system" means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.

(f) "Rating" means the operating limits as specified by the component manufacturer.

(g) "Recording" means producing a permanent form of an image resulting from x-ray photons.

(h) "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction (See "direct scattered radiation").

(i) "Secondary protective barrier" (See "protective barrier").

(j) "Shutter" means a device attached to the tube housing assembly which can intercept the entire cross sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

(k) "SID" (See "source-image receptor distance").

(l) "Source" means the focal spot of the x-ray tube.

(m)"Source-image receptor distance" means the distance from the source to the center of the input surface of the image receptor.

(n) "Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

(o) "Spot-film device" means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

(p) "SSD" means the distance between the source and the skin entrance plane of the patient.

(q) "Stationary x-ray equipment" (See "x-ray equipment").

(r) "Stray radiation" means the sum of leakage and scattered radiation.

R325.XXX8. Definitions T to V.

Rule XXX8. (1) As used in this part:

(a) "Technique factors" means the following conditions of operation:

(i) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

(ii) For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of x-ray pulses;

(iii) For CT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

(iv) For CT x-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

(v) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

(b) "Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

(c) "Tomogram" means the depiction of the x-ray attenuation properties of a section through the body.

(d) "Tube" means an x-ray tube, unless otherwise specified.

(e) "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

(f) "Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

(g) "Type 1100 aluminum alloy" means aluminum that has a nominal chemical composition of 99.00 percent minimum aluminum and 0.12 percent copper.

(h) "Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the system to produce radiation.

(i) "Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.

(j) "Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

R325.XXX9. Definitions X to Z.

Rule XXX9. (1) As used in this part:

(a) "X-ray exposure control" means a device, switch, button or other similar means by which an operator initiates and/or terminates the radiation exposure. The x-ray exposure control may include such associated equipment as timers and back-up timers.

(b) "X-ray equipment" means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

(i) "Mobile x-ray equipment" means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.

(ii) "Portable x-ray equipment" means x-ray equipment designed to be hand-carried.

(iii) "Stationary x-ray equipment" means x-ray equipment which is installed in a fixed location.

(c) "X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

(d) "X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

(e) "X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

(f) "X-ray table" means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography and/or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, image intensifier, or spot-film device beneath the tabletop.

(g) "X-ray tube" means any electron tube which is designed for the conversion of electrical energy into X-ray energy.

R325.XX10. Radiation safety requirements.

The compliance responsibilities are addressed in Part 4 of the rules.

Rule XX10. (1) An x-ray system which does not meet the provisions of these regulations shall not be operated for diagnostic purposes.

(2) Individuals who will be operating the x-ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment. See Appendix A for a list of

subject matters pertinent to this requirement. The agency may use interview, observation and/or testing to determine compliance.

(3) A chart shall be provided in the vicinity of each general purpose diagnostic x-ray system's control panel which specifies, for all examinations performed with that system, the following information:

(a) Patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized.

(b) Type and size of the image receptor to be used.

(c) Type and focal distance of the grid to be used, if any.

(d) Source to image receptor distance to be used (except for dental intra-oral radiography).

(e) Type and location of placement of patient shielding (e.g., gonad, etc.) to be used.

(f) For mammography, indication of kVp/target/filter combination.

(4) The registrant of a facility shall create and make available to x-ray operators written safety procedures, including patient holding and any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.

(5) Except for patients who cannot be moved out of the room, only the staff, ancillary personnel or other persons required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

(a) All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent material;

(b) The x-ray operator, other staff, ancillary personnel, and other persons required for the medical procedure shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.5 millimeter lead equivalent material;

(c) Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.5 millimeter lead equivalent material or

shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

(6) Gonad shielding of not less than 0.5 millimeter lead equivalent material shall be used for human patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

(7) Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

(a) Exposure of an individual for training, demonstration, or other non-healing arts purposes.

(b) Exposure of an individual for the purpose of healing arts screening except as authorized by Rule xxx (healing arts screening below).

(8) When a patient or film must be provided with auxiliary support during a radiation exposure:

(a) Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by subrule (4) above, shall list individual projections where holding devices cannot be utilized;

(b) Written safety procedures, as required by subrule (4) above, shall indicate the requirements for selecting a holder and the procedure the holder shall follow.

(c) Staff personnel routinely working with or around radiation sources shall not be required by the registrant to hold film or restrain patients during radiography. If such procedure is permitted personnel exposure shall not exceed rule 205 or the procedure shall be prohibited.

(d) The human holder shall be instructed in personal radiation safety and protected as required by subrule (5).

(e) No individual shall be used routinely to hold film or patients;

(f) In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material; and

(g) Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with x-ray operations and who are otherwise not shielded.

(9) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

(a) The speed of the screen and film combinations used shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intra-oral use in dental radiography.

(b) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

(c) Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary x-ray installation.

(d) general purpose X-ray systems shall not be utilized in procedures where the source to patient distance is less than 30 centimeters, except for veterinary systems.

(e) If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:

(i) Be positioned properly, i.e., tube side facing the right direction, and grid centered to the central ray.

(ii) If of the focused type, be of the proper focal distance for the SIDs being used.

(10) An operator shall properly utilize the beam-limiting devices provided to restrict the useful beam to the smallest area consistent with clinical requirements. Particular care shall be taken to align accurately the x-ray beam with the patient and film.

(11) The operator shall insure the presence of adequate filtration before any radiographic procedure.

(12) All individuals who are associated with the operation of an x-ray system are subject to the requirements of Part 5 of these regulations.

(13) An x-ray system shall not be left unattended without locking the apparatus, room, or building in some manner that will prevent use of the apparatus by unauthorized persons.

R325.XX11. Personnel Monitoring.

Rule XX11. (1) Personnel monitoring shall be performed in controlled areas for each individual occupationally exposed to ionizing radiation from diagnostic x-ray equipment except dental intraoral. Personnel monitoring devices such as film badge dosimeters or thermoluminescent dosimeters shall be permanently assigned to each occupationally exposed individual. This monitoring shall be continuous during employment as a radiation worker.

(2) Radiologic technologists whose duties require the routine wearing of a protective apron shall be provided with two radiation dosimeters. One dosimeter is used to monitor the dose to the whole body and should normally be worn on the chest or abdomen under the lead apron. A second dosimeter is used to monitor the exposure to the lens of the eye and should be worn at the collar outside of the lead apron.

(3) Exception: Personnel working with extremity fluoroscopes (mini C-arms) and veterinary non-fluoroscopic radiographic equipment may use only one badge that is worn at the collar outside of the lead apron.

(4)

(5) Personnel exposure records shall be kept on permanent available file at the facility where the exposure occurs.

(6) Monitoring devices used to estimate whole body exposure shall normally be worn on the chest or abdomen. Monitoring of any other body part shall comply with rule 222.

(7) Monitoring devices worn to estimate personnel occupational exposure shall not be worn by the individual when he is exposed as a patient for any medical or dental reason.

R325.XX12. Records.

Rule XX12. (1) Except for veterinary facilities, each facility shall maintain a record containing the patient's name, the type of examinations, and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.

(2) The registrant shall maintain records and images from medical imaging procedures for purposes of future access and reference for a period of no less than 7 years. Imaging records for minors shall be maintained until the patient has reached the age of 25.

(3) The registrant shall have a policy in place for proper patient image and record handling in the event that the facility ceases operations. A facility that is ceasing operations must either transfer its medical records to another facility and notify the patient of the transfer, or provide the medical records to its patients.

R 325.XX13. X-ray system information records.

Rule XX13. (1) The registrant shall maintain the following information for each x-ray system for inspection by the department:

(a) Model and serial numbers of all major components, and user's manuals for those components.

(b) Tube rating charts and cooling curves.

(c) Records of surveys, calibrations, maintenance, and modifications performed on the x-ray system(s).

(d) A copy of all correspondence with this department regarding that x-ray system.

R325.XX14. X-ray film processing facilities and practices.

Rule XX14. (1) For manual developing, each installation using a radiographic x-ray system and using analog image receptors (e.g. radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

(a) Processing tanks shall be constructed of mechanically rigid, corrosion resistant material.

(b) The temperature of solutions in the tanks shall be maintained within the range of 60 °F to 80 °F (16 °C to 27 °C). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the following time-temperature chart:

Time-Temperature Chart		
Thermometer Reading (Degrees)		Minimum Developing Time (Minutes)
°C	°F	
26.7	80	2
26.1	79	2
25.6	78	2½

25.0	77	2½
24.4	76	3
23.9	75	3
23.3	74	3½
22.8	73	3½
22.2	72	4
21.7	71	4
21.1	70	4½
20.6	69	4½
20.0	68	5
19.4	67	5½
18.9	66	5½
18.3	65	6
17.8	64	6½
17.2	63	7
16.7	62	8
16.1	61	8½
15.6	60	9½

(c) Devices shall be utilized which will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

(2) For automatic developing, each installation using a radiographic x-ray system and using analog image receptors (e.g. radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

(a) Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer; in the absence of such recommendations, the film shall be developed using the following chart:

Developer Temperature		Minimum Immersion Time[a]
°C	°F	Seconds
35.5	96	19
35	95	20
34.5	94	21
34	93	22
33.5	92	23
33	91	24
32	90	25
31.5	89	26
31	88	27
30.5	87	28
30	86	29
29.5	85	30

[a] Immersion time only, no crossover time included.

(b) The specified developer temperature and immersion time shall be posted in the darkroom or on the automatic processor.

(3) Processing deviations from the requirements of Rule xxx(1) and (2) shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing, and special rapid chemistry).

(4) Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

(5) The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from 1 to 2 when processed shall not suffer an increase in density greater than 0.1 (0.05 for mammography) when exposed in the darkroom for 2 minutes with all safelights on. Darkrooms with fluoroscent general lighting must be tested for fogging due to potential afterglow, immediately after turning these lights off. If used, daylight film handling boxes shall preclude fogging of the film.

(6) Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

(7) Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

(8) Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality.

(9) Outdated x-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

(10) Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

R325.XX15. X-ray equipment.

Rule XX15. (1) Warning Label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

(2) Battery Charge Indicator. On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

(3) Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 25.8 micro Coulombs/Kg (100 milliroentgens) in 1 hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(4) Radiation from Components Other Than the Diagnostic Source Assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 0.5 micro Coulombs/Kg (2 milliroentgens) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(5) Half-Value Layer. The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made. For capacitor energy storage equipment, compliance with the requirements of this rule shall be determined with the system fully charged and a setting of 10 mAs for each exposure. The required minimal half-value layer of the useful beam shall include the filtration contributed by all materials which are permanently between the source and the patient.

Table I		
Design Operating Range	Measured Potential (kVp)	Half-Value Layer in mm Aluminum

		Dental Intra-Oral	All Other Diagnostic X-Ray Systems
Below 51	30	N/A	0.3
	40	N/A	0.4
	50	1.5	0.5
51 to 70	51	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

(6) Filtration Controls. For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration necessary to produce the HVL required by R325.XX15(5) is in the useful beam for the given kVp which has been selected.

(7) Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly that has been selected.

(8) Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.

(9) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors that are set prior to the exposure shall be indicated. This requirement may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(10) Beam Limitation, Excluding Mammographic, Fluoroscopic, Dental Intraoral, and Computed Tomography X-Ray Systems. The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam limiting device meeting manufacturer's specifications and the requirements of Rule 329(b), if applicable, has been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).

(a) General Purpose Stationary and Mobile X-Ray Systems, Including Veterinary Systems (Other than Portable) Installed After the Effective Date of These Regulations.

(i) Only x-ray systems provided with means for independent stepless adjustment of at least two dimensions of the x-ray field shall be used.

(ii) A method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(iii) The department may grant an exemption on non-certified x-ray systems to Rule XX15(10)(a)(i and ii) above provided the registrant makes a written application for such exemption and in that application:

(A) Demonstrates it is impractical to comply with rule XX15(10)(a)(i and ii); and

(B) The purpose of rule XX15(10)(a)(i and ii) will be met by other methods.

(b) Additional Requirements for Stationary General Purpose X-Ray Systems. In addition to the requirements of rule XX15(10)(a), stationary general purpose x-ray systems, both certified and noncertified, shall meet the following requirements:

(i) A method shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;

(ii) The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and

(iii) Indication of field size dimensions and SIDs shall be specified in inches and/or centimeters, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(c) X-Ray Systems Designed for One Image Receptor Size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(d) X-Ray Systems Other Than Those Described in rule XX15(10)(a, b, and c), and Veterinary Systems Installed Prior to the Effective Date of These Regulations and all Portable Veterinary X-Ray Systems.

(i) Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(ii) Means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of

the image receptor. Compliance shall be determined with the axis of the x-ray beam perpendicular to the plane of the image receptor.

(iii) rule XX1510)(d)(i and ii) may be met with a system that meets the requirements for a general purpose x-ray system as specified in rule XX15(10)(a) or, when alignment means are also provided, may be met with either:

(A) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(B) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

(11) Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action. In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(12) Means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, for radiographic systems, a signal audible to the operator shall indicate that the exposure has terminated.

(13) Excluding fluoroscopic systems, means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero." It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

(14) An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for:

(a) Exposure of 1/2 second or less.

(b) During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

(15) When an automatic exposure control is provided:

(a) Indication shall be made on the control panel when this mode of operation is selected.

(b) If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to 2 pulses.

(c) The minimum exposure time for all equipment other than that specified in 13(b) above shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver 5 mAs, whichever is greater.

(d) Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the x-ray tube potential is less than 50 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure.

(e) A visible signal shall indicate when an exposure has been terminated at the limits required by 13(d) above, and manual resetting shall be required before further automatically timed exposures can be made.

(16) For systems having independent selection of exposure time settings, the average ratios (X_i) of exposure to the indicated timer setting, in units of C $kg^{-1}s^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average C $kg^{-1}s^{-1}$ (mR/s) values.

Timer Linearity.

(17) When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.05. This requirement applies to clinically used techniques.

Manual/AEC Reproducibility.

(18) Deviation of measured technique factors from indicated values of kVp and exposure time shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10 percent of the indicated value for kVp and 20 percent for time.

Timer/kVp Accuracy.

(19) The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated:

(a) Equipment Having Independent Selection of X-Ray Tube Current (mA). The average ratios (X_i) of exposure to the indicated milliampere-seconds product (C kg^{-1} mAs^{-1} (or mR/mAs)) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 < 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of 2 where the tube current selection is continuous.

(b) Equipment Having a Combined X-Ray Tube Current-Exposure Time Product (mAs) Selector, But Not a Separate Tube Current (mA) Selector. The average ratios (X_i) of exposure to the indicated milliampere-seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 < 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two mAs selector settings, or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(c) Measuring Compliance. Determination of compliance shall be based on 10 exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

(20) Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the Federal X-Ray Equipment Performance Standard (21 CFR Part 1020) shall be maintained in compliance with applicable requirements of that standard.

(21) All position locking, holding, and centering devices on x-ray system components and systems shall function as intended.

R325.XX16. Mobile or portable equipment and use.

Rule XX16. (1) Mobile or portable diagnostic x-ray equipment shall not be used for routine radiography or fluoroscopy in hospitals or private offices of practitioners of the healing arts. This

equipment shall only be used when it is medically inadvisable to move a patient to a fixed radiographic or fixed fluoroscopic installation.

(2) Portable shielding of 1.6 millimeter (1/16 inch) lead equivalent shall be used by the operator and others in the room when possible.

(3) Individuals operating mobile or portable diagnostic x-ray equipment shall wear a protective apron of minimum 0.5 millimeter lead equivalence unless portable shielding is provided as specified in subrule (2) above.

Moved here from previous Part 7.

(4) All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 centimeters.

(5) A tube stand or other mechanical support shall be used for portable x-ray systems, so that the x-ray tube housing assembly need not be hand-held during exposures.

R325.XX17. Enclosures and radiation shielding.

Rule XX17. 1) An enclosure shall be a permanent part of the building or equipment. Portable shields shall not be used for permanent installations.

(2) The degree of protection required for an enclosure shall be determined by the workload, use and occupancy factors and the kilovoltage, milliamperage, mechanical movement and distance factor, and shall be subject to design approval by the department. Recommended shielding appears in rule 357.

(3) Radiographic-room wall and floor areas exposed to the useful beam plus an additional area extending at least 30 centimeters (1 foot) beyond shall be provided with a primary protective barrier where necessary as determined by workload, use, occupancy and distance factors. All vertical primary protective barriers specified in this rule shall extend continuously from the floor to a minimum height of 2.1 meters (7 feet).

(4) Secondary protective barriers shall be provided in the radiographic room ceiling, floor, and in those walls not requiring primary barriers.

Previous omission corrected by adding floors as secondary barriers also.

(5) Mobile or portable diagnostic x-ray equipment used routinely in 1 location shall be considered a fixed installation and shall comply with all applicable shielding requirements for fixed installations.

The general enclosures rules are moved here from previous part 7. Specific shielding requirements for each use are in their respective parts.

R325.XX18. Quality assurance and quality control.

Rule XX18. (1) One year after the effective date of these rules, each medical diagnostic x-ray facility must develop and implement a quality assurance program which includes, at a minimum, the following:

(a) A quality control manual that is reviewed annually and includes facility objectives, QC test frequency and instructions, QC test results, and personnel responsibilities.

(b) Quality Control tests shall be conducted for, at a minimum, system constancy, film processing, repeat analysis, intensifying screen cleaning, and darkroom fog.

(c) A quality assurance coordinator shall be designated to be responsible for maintaining the QA program and assuring compliance with these rules.

Guidance for quality assurance programs is available from the department. (CRCPD QC recommendations for diagnostic radiography volumes 1-3)

(OR INSERT CRCPD QC RECOMMENDATION VOLUMES 1-3 HERE?)

PHASE-IN WILL BE NEEDED.

PART 6

APPENDIX A

DETERMINATION OF COMPETENCE

The following are areas in which the agency considers it important that an individual have expertise for the competent operation of x-ray equipment:

(a) Familiarization with equipment

(1) Identification of controls

(2) Function of each control

(3) How to use a technique chart

(b) Radiation Protection

(1) Collimation

(2) Filtration

(3) Gonad shielding and other patient protection devices if used

(4) Restriction of x-ray tube radiation to the image receptor

(5) Personnel protection

(6) Grids

(c) Film Processing

(1) Film speed as related to patient exposure

(2) Film processing parameters

(3) Quality assurance program

(d) Emergency Procedures

(1) Termination of exposure in event of automatic timing device failure

(e) Proper Use of Personnel Dosimetry, if Required

(f) Understanding Units of Radiation